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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/425,956	10/25/1999	RUDOLPH E. TANZI	0609.4110001	1225

26111 7590 01/02/2004

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EXAMINER	
DUFFY, PATRICIA ANN	

ART UNIT	PAPER NUMBER
1645	25

DATE MAILED: 01/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/425,956	Applicant(s) TANZI ET AL.	
	Examiner Patricia A. Duffy	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 July 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

RESPONSE TO AMENDMENT

The response filed July 7, 2203 has been entered into the record. Claims 1-30 are pending and under examination.

The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

Rejections Maintained

Claims 1-30 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 5,972,634. Although the conflicting claims are not identical, they are not patentably distinct from each other because the term "antibody" of the patent is inclusive of both polyclonal and monoclonal antibodies.

Applicants previously indicated that a terminal disclaimer will be filed upon notice of a allowable subject matter. The rejection is maintained until such time that it obviated by amendment of the claims, argument or a properly filed terminal disclaimer.

Claims 5-16 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for all reasons made of record in Paper Nos. 11, 15 and 20.

Applicants' arguments have been again carefully considered but are not persuasive for reasons already made of record. Applicants maintain their position that identifying specific immunogens would have been a matter of routine experimentation. This is not persuasive for reasons made of previously made of record. The immunogens and particular methodology used to make the polyclonal antibody of the post-filing art of Mak et al and Oncogene Products were not "prior art" at the time that this invention was made and these immunogens and series of immunosorbent columns used to arrive at the polyclonal antibodies were not provided in the written description of the specification as originally filed. Further, it is noted that Mak et al provided as Exhibit 5 in the response teaches that even with specific adsorption that the anti-42 antibody brought down a fraction of the B40 (see page 139, column 1 and Figure 2). As such, it appears that adsorption does not predictably lead to a polyclonal antibody that does not bind the opposite member. Applicants also state that there were other methods using the immunogens of the specification (B1-40 and B1-42)that would lead to non-cross reactive polyclonal antibodies using the adsorptive techniques of the art and describes a hypothetical procedure. This is not persuasive in view of the teaching of Mak et al which indicates that immunoadsorption

techniques are unpredictable at adsorption of non-cross reactive antibodies. Further, the methodology as asserted lacks any evidentiary support that the retained antibodies resulting therefrom are non-cross reactive as required by the claims. Applicants' assertions remain unsupported by evidence that known methodology using the immunogens and adsorptions provide for antibodies with the requisite claimed specificity. As to Exhibits 1-4, these are conventional immunosorbent techniques in the art that are asserted by Applicants that could be used with the peptides set forth in the specification. This is not persuasive for reasons set forth *supra*. As to Mak et al Exhibit 5, the problems with the immunogens and adsorptive members to predictably and reproducibly generate the claimed antibodies for use in the assay were addressed above. Therefore, Mak et al, using immunogens and particular adsorptive methods not disclosed in the specification as filed, remains not persuasive. As to Exhibits, 6, 7 and 8, these are publications that are published well after the filing date of this Application and do not establish what one skilled in the art would have believed at the time that this Application was filed. As stated in In re Wright 27 USPQ2d 1510, 1512 (CAFC 1993), the issue is not what the state of the art is today or what a skilled artisan today would believe, but rather what the state of the art at the time of filing and what a skilled artisan would have believed at that time. Hybritech Inc. v. Monoclonal Antibodies, Inc. 802 F2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir.), cert denied, 480 U.S. 947 (1987); In re Hogan, 559 F2d 595, 604, 194 USPQ 527, 535 (CCPA 1977).

The rejection is maintained.

Claims 5-16 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Applicants' arguments have been carefully considered but are not persuasive. Applicants reiterate the language of the specification indicating that the language of the specification is sufficient to indicate that they were in possession of the claimed invention because non-cross reactive antibodies were common place in the art as per remarks in Section IV.A of their response. This is not persuasive because the claimed non-cross reactive beta amyloid polyclonal antibodies have not been established as common place in the art at the time that this Application was filed. In fact, all the art hereto provided indicates that the particular immunogens and methods and protocols to establish such, were not common place to the Alzheimer's art, nor were the polyclonals or methodology to make them in the prior art. As such, one skilled in this art would clearly recognize that Applicants were not in possession of the claimed polyclonal antibodies for use in the assay of the invention. Because Applicants were not in possession of the disputed polyclonal antibodies, they could not possibly have been in possession of the methods that employ

these particular polyclonal antibodies. Antibodies that bind other antigens are not the issue here. What is at issue is possession and written description of the polyclonal antibodies for use in the claimed assay. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.

The rejection is maintained.

Status of Claims

All claims stand rejected.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy whose telephone number is 703-305-7555 or 571-272-0855 after January 27, 2003. The examiner can normally be reached on M-F 6:30 pm - 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Smith Lynette can be reached on 703-308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Patricia A. Duffy

Primary Examiner

Art Unit 1645